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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,124

06/16/2006

Aldo Giannozzi

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6885

27476

7590

07/22/2008

NOVARTIS VACCINES AND DIAGNOSTICS INC.

INTELLECTUAL PROPERTY R338

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

07/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,124	<b>Applicant(s)</b> GIANNOZZI ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-43 is/are allowed.
- 6) ☒ Claim(s) 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/09/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 04/07/08.

The amendment filed 04/07/08 affects the application, 10/526,124 as follows:

1. Claims 1, 4, 6, 8-10, 13-15, 17, 18, 20, 22, 24, 25, 27, 28, 30, 32-36, 38, 39, 43-45 have been amended. New Claim 46 has been added. Applicant's amendment has overcome the objections made under 37 CFR 1.75(c), the rejections made under 35 U.S.C. 112, second paragraph and under 35 U.S.C. 102(b). Consequently, the said rejections are withdrawn. However, a new ground(s) rejection is set forth herein.
2. The responsive to applicants' arguments is contained herein below.

Claims 1-46 are pending in application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for preventing specific disease such as meningitis which is caused by a capsulate bacterial in a mammal comprising administering to the mammal the conjugate of claim 33, does not reasonably provide enablement for preventing said disease in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without *undue experimentation*. Attention is directed to *In*

*re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a method for preventing a disease caused by one or more capsulate bacterial in a mammal comprising administering to the mammal the conjugate of claim 33.

The relative skill of those in the art: The relative skill of those in the art is high. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a preventive therapeutic mode of administration and the skilled artisan could not immediately envisage the invention claimed.

The breadth of the claims: The instant claims are deemed very broad since these claims reads on preventing a method for preventing a disease caused by one or more capsulate bacterial in a mammal comprising administering to the mammal the conjugate of claim 33.

Regarding the *Wands* factor (4) the predictability or unpredictability of the art:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is

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necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that the recitation encompasses preventing a disease caused by one or more capsulate bacterial in a mammal comprising administering to the mammal the conjugate of claim 33, which are not known to have a single recognized cause. Applicant claims a method for prophylaxis or preventing a disease caused by one or more capsulate bacterial, in a mammal, which is not generally known to exist in this art; additionally, the disclosure is silent with regard to that which makes up and identifies the claimed method for preventing the said disease, which is seen to be lacking a clear description via art recognized procedural and methodological steps. In addition, the said disease does not have a single recognized cause. Furthermore, the said disease(s) (which include septicaemia, gonorrhoea, otitis media, bronchitis, pneumonia, cellulitis, pericarditis, meningitis and sepsis) can be caused by various capsulate bacteria. Also, and as example, lower respiratory infections, which include various pneumonias, and diarrheal diseases are caused by many different bacteria. Moreover, the aforementioned disease is recognized as having many contributing factors, ranging from hereditary considerations, to lifestyles choices such as the diet and maintenance of bodily healthiness. These contributing factors, which including altered genes, chemicals, aging and infections, can make someone more susceptible to disease. These are only a few of the factors that promote these diseases in humans or mammals. Furthermore, the bacterial diseases or infections are caused or transmitted via various modes such as via exposure to contaminated food (e.g. chicken) and water, contact with infected animals (e.g. cats and puppies) and through contaminated meat, drinks, and fruits and vegetables. Also, every human being is exposed to innumerable bacteria, some of are at higher risk of infection than others. These risk factors

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include a weakened immune system, age, diet or nutritional status, and genetic predisposition.

Applicant has not provided a description as to how any cause (like the aforementioned) can be prevented much less a description of how the said disease can be prevented. Furthermore,

Applicant has not provided any clear description via art recognized procedural and methodological steps. Moreover, Applicant has not provided an adequate representation of the mode of treatment of said diseases to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention by preventing said disease. Therefore, the prevention of the said diseases in a mammal is not enabled by the instant disclosure.

Thus, the skilled artisan would view that the prevention of a disease caused by one or more capsulate bacterial in a mammal by administering to said mammal the specific compound herein, as being highly *unpredictable*.

In regard to these *Wands* factors, (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary:

Moreover, it is noted that the specification provides no working examples to the prevention of said disease(s).

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the prevention of a disease caused by one or more capsulate bacterial in a mammal in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of preventing said disease in any mammal as recited in the instant claims suitable to practice the claimed invention. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in

the art and no evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed method with a reasonable expectation of success. Therefore, the prevention of disease caused by one or more capsulate bacterial in a mammal by the said method is not enabled by the instant disclosure.

*Genentech*, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation, with no assurance of success.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

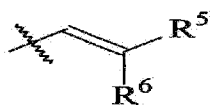
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 46 is rejected under 35 U.S.C. 102(b) as being anticipated by Eagle et al. (Journal of Chemical Research Synoses (1993), (10), 390) (Abstract Only).

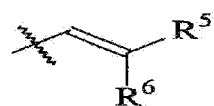
Claim 46 is drawn to a modified capsular saccharide comprising a moiety of the formula (I): -A-N(K1)-L-M wherein: A is a bond, -C(O)- or -OC(O)- ; R<sup>1</sup> is selected from H or C<sub>1</sub>-C<sub>6</sub>

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alkyl; L is a C<sub>1</sub>-C<sub>12</sub> alkylene group; M is a masked aldehyde group, wherein the masked aldehyde

is selected from: .....  .....

Eagle et al. disclose applicant's saccharide of the formula (I) wherein A is -OC(O)- ; R<sup>1</sup>

is H, L is a C<sub>9</sub> alkylene group and M is a masked aldehyde group,  wherein R<sup>5</sup> = H and R<sup>6</sup> = C<sub>4</sub> alkyl (i.e., n-butyl) or vice versa (see abstract). Eagle et al.'s saccharide has the Cas # 153214-94-9 (see abstract).

### *Response to Amendment*

Applicant's arguments with respect to claims 44-46 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



***Allowable Subject Matter***

The examiner has found claim 1-43 to be unobvious over the prior art of record and may therefore be allowable over the prior art of record. Claims 1-43 are drawn to specific modified capsular oligosaccharide or polysaccharide, conjugates, and a method of modifying and using said compounds. The prior art does not teach or suggest the specific modified capsular oligosaccharide or polysaccharide, conjugates or the method of modifying and using said compounds as set forth in said claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

July 16, 2008.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623